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January 29, 2025

Via ECF

The Hon. Renée Marie Bumb
United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Special Master the Hon. Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower, 18th Floor
Philadelphia, PA 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*
USDC, District of New Jersey, No. 1:19-md-2875-RMB

Dear Judge Bumb and Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on Friday, January 31, 2025.

1. Resumption of Regular PFS Deficiency/Orders to Show Case Process

Early in this MDL proceeding, the Court established a process for Defendants to seek and obtain dismissals in cases where individual Plaintiffs fail to provide necessary information in their Plaintiff Fact Sheet ("PFS"). This procedure is set forth in CMO 16 and provides that after two sequential listings of a deficient case in the agenda for the Court's CMC, the Court will proceed to enter an order to show cause returnable at the next CMC requiring the delinquent party to show why their complaint should not be dismissed with prejudice. (ECF No. 249).

Through this process, the parties have historically worked amicably to resolve and reduce such disputes, leaving only a handful of issues for the Court to resolve and/or orders to enter at each

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monthly CMC. Since the first setting of the TPP trial in March 2024 and the reassignment, this process has been on hold. Defendants request that the Court reinstitute the monthly show cause process, following the format previously utilized, at the next CMC following the January 31, 2025 CMC. The parties have met and conferred over this request and Defendants understand that Plaintiffs have no objection to continuing this process. The parties are prepared to resume meeting and conferring on outstanding deficiencies and to present a listing of cases at the next CMC.

To the extent the Court has any questions about the PFS Deficiency/Order to Show Cause process, Defendants will be prepared to discuss those issues at the January 31 CMC.

2. Proposed Product Identification Dismissal/Show Cause Process

The Court's renewed focus on the personal injury bellwether cases makes it imperative that the parties work together to update and ensure the accuracy of the existing personal injury case inventory in this long-running MDL. Defendants propose that the Court implement a new show cause process to enable Defendants to obtain dismissals in cases where a Defendant is identified in the operative complaint but the individual Plaintiff has not produced records demonstrating product ID for said Defendant(s). Given the effectiveness of the existing PFS Deficiency process at narrowing and limiting disputes, Defendants propose that a similar structure would be most efficient and comport with due process. In summary: (1) defense counsel directly contacts individual Plaintiff's counsel about the alleged deficiency, (2) Plaintiffs' counsel are further notified by Defendants through Plaintiffs' designated leadership counsel of all potential product ID deficiencies to be listed at a given CMC, (3) a global meet and confer is scheduled for interested parties to attend and discuss any alleged deficiencies, (4)

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the case is listed on at least two consecutive position statements filed publicly on ECF, and (5) the Court would then enter an order to show cause returnable at the next CMC as to why certain Defendants should not be dismissed for lack of product identification.

Some of the parties have had partial success negotiating informally to reach voluntary dismissals for lack of product ID, and we anticipate that process would continue. The present proposal simply formalizes that process and gives Defendants the opportunity to seek Court intervention when there is a legitimate dispute or (much more commonly) when the informal request does not receive a response. Defendants raised this proposal with Plaintiffs during a meet and confer held on January 28, 2025. Plaintiffs acknowledge that it is appropriate to ensure parties are dismissed where product ID is absent, but propose that the parties work informally to obtain such dismissals without the need for a formal process like the one outlined above. Defendants have agreed to continue to meet and confer with Plaintiffs over the next month to determine if these product ID issues can be resolved in a manner not requiring the Court's intervention, but will revisit this issue at a later date if needed.

3. Plaintiffs' Motion to Establish Common Benefit Assessments and Common Benefit Fund

On January 15, 2025, Plaintiffs filed a Motion to Establish Common Benefit Assessments and Common Benefit Fund. (ECF No. 2960). While Defendants generally do not object to the motion, the proposed Common Benefit Order (ECF No. 2960-12) imposes certain obligations on Defendants. Defendants have informally raised certain issues with Plaintiffs related to those obligations, and Plaintiffs have agreed to meet and confer on these issues. Defendants are hopeful that this matter can be resolved without Court intervention. Defendants ask that the

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Court not enter the Common Benefit Order until the parties have had the opportunity to complete the meet and confer.

4. Defendants' Selection of Remaining Wave 2 Bellwether Pool Cases

Plaintiffs' timing in raising *Lexecon* has resulted in a trial pool overwhelmingly stocked with Plaintiff-selected bellwethers, and Defendants should be allowed to select the two Wave 2 replacement cases to restore balance to the bellwether pool.

On January 17, 2025, Plaintiffs filed a letter confirming that the individual Plaintiffs in *Dufrene* and *Meeks*, selected randomly from a list of matters for which participating Manufacturer Defendants had already been required to confirm they would waive *Lexecon* to permit the case be tried in the District of New Jersey, would not be waiving *Lexecon* and therefore removing those cases from the Wave 2 bellwether pool. As previewed by defense counsel during the January 13, 2025 Status Conference, the asymmetrical manner in which Plaintiffs and Defendants have been required to evaluate and exercise *Lexecon* rights has created a Wave 2 bellwether pool skewed overwhelmingly in favor of cases selected by Plaintiffs.

To briefly recount what has transpired in the months since the Court indefinitely suspended the TPP trial set for November 2024, the first case currently set for trial in September 2025, *Gaston Roberts*, the only liver cancer case in the bellwether pool, was a Plaintiffs' bellwether pool selection hand-picked by Plaintiffs. (*See* ECF No. 2911 at (proposing "[t]e first bellwether trial should be a single-plaintiff liver cancer case against only the ZHP API and other downstream defendants")). Judge Vanaskie then randomly selected five additional matters from among the remaining 27 bellwether pool cases on October 22, 2024, to potentially comprise "Wave 2." (ECF No. 2912). All five of those matters were identified to have either subject

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matter jurisdiction issues or be predicated on claims against manufacturer defendants who could potentially assert *Lexecon* rights, thereby preventing the cases from being tried in the District of New Jersey. (See ECF Nos. 2914 at 1-2; 2922; 2925).

At the December 4, 2024 Status Conference, Judge Vanaskie instructed the parties to meet and confer and identify cases involving only product manufactured by the ZHP, Teva, and Torrent Defendants to submit for potential inclusion in a revised Wave 2 bellwether pool, as those parties either do not have or do not intend to exercise *Lexecon* rights in connection with the bellwether pool cases.

Counsel for the ZHP, Teva, and Torrent Defendants met and conferred with Plaintiffs' counsel on December 10, 2024, to identify cases meeting the stated criteria. During this meet and confer, the parties agreed that the following cases – 4 of which were originally selected for the bellwether pool by Defendants and 5 by Plaintiffs – could be tried in the District of New Jersey, subject to Plaintiffs' decisions as to whether they would dismiss downstream pharmacy and wholesaler Defendants:

- Bonmon
- Crawford
- Dufrene
- Garcia
- Lee
- Meeks
- Smalls
- Suits
- Weygant

Following this meet and confer, Plaintiffs submitted a letter on December 17, 2024, identifying these cases as meeting Judge Vanaskie's criteria, (ECF No. 2947), and the parties again confirmed these cases by name at the status conference on December 18, 2024, (12/18/2024 Hrg.

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Tr. at 15 (identifying the seven eligible cases in addition to *Dufrene* and *Meeks* which had been randomly selected on December 16, 2024)).¹ Accordingly, defense counsel for the Manufacturer Defendants understood and expected that Plaintiffs in each of these cases were similarly willing to waive *Lexecon* and permit the cases to be tried in the District of New Jersey. As discussed in more detail below, Plaintiffs' counsel subsequently revealed, after Judge Vanaskie's third attempt at random selection, that they had not evaluated or discussed potential *Lexecon* waivers in some or all of these individual cases, and they began notifying Defendants that they would not waive *Lexecon* in certain of these cases (notably only in cases that were defense bellwether picks). In contrast, the exercise or waiver of *Lexecon* rights where applicable by certain Manufacturer Defendants was done *prior* to further random selection of cases by Judge Vanaskie, and it was done across the board.² No Defendant at any level of the supply chain has selectively exercised their *Lexecon* rights in a given bellwether pool case while agreeing to waive said rights in another matter.

Specifically, the revised Wave 2 pool tentatively selected by Judge Vanaskie on December 31, 2024, included three cases originally added to the bellwether pool by Defendants – *Dufrene*, *Garcia*, and *Meeks* – and two added by Plaintiffs – *Smalls* and *Suits*. (ECF No. 2949). While attempting to contact individual Plaintiff's counsel and discuss potential dismissal of downstream

¹ The December 16, 2024 Order entered before the parties provided Judge Vanaskie with their updated list of eligible cases included three matters which both sides agree make those cases ineligible for the Wave 2 pool, and therefore those tentatively designated cases were removed and three new matters selected. (See ECF Nos. 2944, 2946, 2947).

² Contrary to plaintiffs' assertions, the Aurobindo defendants have not refused to waive *Lexecon* rights. Rather, Aurobindo made a proposal concerning *Lexecon* waiver to plaintiffs, and plaintiffs made a counter-proposal to Aurobindo. Aurobindo has proposed to engage in further discussions with plaintiffs in an effort to resolve the issue, which is closely related to the issue of plaintiffs' assertion of claims against Aurobindo Pharma L.P., which contests personal jurisdiction.

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defendants in these matters, defense counsel learned that the Plaintiff in *Dufrene* likely intended to exercise her *Lexecon* rights. Defendants raised the potential issue of selective exercise of *Lexecon* waivers at this stage of the selection process ahead of the January 13, 2025 Status Conference, (ECF No. 2955), and requested that counsel for each of the Wave 2 bellwether pool Plaintiffs be present at that conference, (ECF No. 2953).

At the January 13, 2025 Status Conference, counsel for *Dufrene* confirmed that Plaintiff would be exercising her *Lexecon* rights. (1/13/2025 Hrg. Tr. at 7-8, 11). Counsel for *Suits* (a Plaintiff pick) and *Garcia* (a defense pick) both indicated their clients would waive *Lexecon* and dismiss any downstream entities as needed to enable the case to be tried in the District of New Jersey. (*Id.* at 8-9). Counsel representing both *Meeks* (a defense pick for the pool) and *Smalls* (picked by Plaintiffs) could not confirm whether her clients would waive *Lexecon*. (*Id.* at 9-10). Judge Vanaskie ordered these Plaintiffs to confirm whether they would waive by January 17, 2025.

In Plaintiffs' January 17, 2025 Letter to Judge Vanaskie (Ex. 1), Plaintiff in *Meeks* indicated they would not be waiving *Lexecon*, removing yet another defense-selected case from the Wave 2 pool. Plaintiffs in every case where downstream Defendant *Lexecon* waivers were identified as a potential issue have agreed to dismiss those entities. (*Id.*).

Despite best efforts to identify a representative set of cases to be worked up as part of the Wave 2 bellwether pool, the current pool of three matters contains only a single defense selected case, and the pool of four eligible replacement cases contains only a single case chosen by Defendants. Notably, *Crawford*, the only defense pick eligible to serve as a replacement, is a ZHP-only case involving no other manufacturer defendants. For Teva, the only other manufacturer

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defendant involved in Wave 2 following *Dufrene*'s exercise of her *Lexecon* rights, every eligible replacement case involving Teva entities was added to the bellwether pool by Plaintiffs' counsel.

Defendants submit that the sole appropriate remedy to restore some semblance of balance and fairness to the Wave 2 pool is to allow Defendants to select the replacement cases from among the four eligible matters rather than again proceeding by random selection.

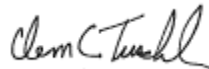
5. Wave 3 Bellwether Pool Cases

Plaintiffs and Defendants have initiated the meet and confer process related to Wave 3 bellwether cases. The parties agree that these discussions will continue after the Court finalizes the list of cases for Wave 2 and establishes a corresponding case management schedule for the workup of the Wave 2 cases for trial.

6. Discovery Issues Related to ZHP

ZHP has been working cooperatively with Plaintiffs with respect to a proposed stipulation to address Plaintiffs' request for certificates of analysis and material safety data sheets. ZHP continues to believe that a stipulation is the most efficient way to resolve Plaintiffs' requests and is optimistic that the parties will be able to address this issue without Court intervention. The parties are scheduled to meet and confer further on this issue and will be prepared to provide the Court with an update at the January 31, 2025 CMC.

Respectfully submitted,



Clem C. Trischler

c: All counsel of record (via ECF)